

VITAMIN, MINERAL, AND OTHER PRODUCTS OF SPECIAL DIETARY SIGNIFICANCE

29189. Hespernate tablets. (F.D.C. No. 48776. S. No. 65-103 V.)

QUANTITY: 118 btls. at St. Clairsville, Ohio.

SHIPPED: 8-15-62, from Long Island City, N.Y., by Nysco Laboratories.

LABEL IN PART: (Btl.) "180 Tablets Hespernate A Prenatal Dietary Supplement Manufactured For Scot Pharmacal Co., Inc. St. Clairsville, Ohio Each—Tablet Contains:—Folic Acid 0.13 MGM.—Dosage: 1 or 2 Tablets 3 Times Daily."

LIBELED: 5-14-63, S. Dist. Ohio.

CHARGE: 402(a)(2)(C)—when shipped, contained a food additive, namely, folic acid, which was unsafe within the meaning of 409 since it and its use or intended use were not in conformity with a regulation or exemption in effect pursuant to 409.

DISPOSITION: 11-1-63. Default—destruction.

29190. Multivitamin tablets. (F.D.C. No. 49238. S. Nos. 39-113/4 V.)

QUANTITY: 388 btls. at Brooklyn, N.Y.

SHIPPED: In January 1963, from Dallas, Tex. This was a return shipment.

RESULTS OF INVESTIGATION: Examination showed that one portion of the article contained about 13 percent of declared amount of vitamin D and about 50 percent of declared amount of vitamin B₁ and that another portion of the article contained about 24 percent of declared amount of vitamin D.

LIBELED: 8-29-63, E. Dist. N.Y.

CHARGE: 402(b)(1)—while held for sale, valuable constituents, vitamins D and B₁, had been in part omitted or abstracted from the article; and 403(a)—the label statements "Each Tablet Contains: * * * Vitamin D 500 USP Units * * * Vitamin B₁ (Thiamin Mononitrate) 3 mg." were false and misleading as applied to a product containing less than the declared amounts of these vitamins.

DISPOSITION: 10-3-63. Default—destruction.

29191. Vitamin tablets. (F.D.C. No. 49083. S. No. 26-692 V.)

QUANTITY: 8 cases, 48 bottles each, at Detroit, Mich.

SHIPPED: 8-1-62, from Newark, N.J., by Lit Drug Co.

LABEL IN PART: (Btl.) "100 Tablets Arlan's Geriatric Vitamins * * * Arlan's Dept. Stores, New York, N.Y."

RESULTS OF INVESTIGATION: Examination showed that some of the tablets failed to disintegrate after 4 hours in simulated gastric fluid test solution and in simulated intestinal fluid test solution when tested by use of methods in the United States Pharmacopeia, an official compendium. Examination by human availability assay methods also confirmed such failure of the article to disintegrate.

LIBELED: 6-18-63, E. Dist. Mich.

CHARGE: 402(b)(2)—when shipped, an article which failed to disintegrate had been substituted in part for an article which would disintegrate to permit adequate assimilation of its nutrients; and 403(a)—the label, considered in its entirety, represented and suggested that the declared nutrients of the article

as normally administered are assimilable in the human body, which representations and suggestions were false and misleading since the article failed to disintegrate, so as to permit adequate assimilation of its declared nutrients.

DISPOSITION: 9-12-63: Consent—destruction.

MISCELLANEOUS FOODS

29192. Rodelle Sweet-Tone Preservative. (F.D.C. No. 47217. S. No. 20-828 T.)

QUANTITY: 27 1-gal. jars, at San Antonio, Tex.

SHIPPED: 11-3-61 and 11-4-61, from Denver, Colo, by Rodelle Laboratories, Inc.

LABEL IN PART: (Jar) "Rodelle Sweet-Tone Preservative and Flavor Improver Antiputrefactive Agent to Prevent Growth of Mold and Fermentation Contains: Water, Benzoate of Soda, Propylene Glycol, and Propyl Paraben (A Derivative of Benzoic Acid) Manufactured by Rodelle Laboratories, Incorporated, Denver, Colorado."

LIBELED: 3-12-62, W. Dist. Tex.

CHARGE: 403(a)—while held for sale, the label of the article bore false and misleading representations that the article improved the flavor of foods, and was adequate and effective as a preservative and to prevent growth of mold and fermentation generally in whipped cream goods, cream pie fillings, eclair fillings, pumpkin pie, crusts, candy centers, fondants, and butter creams.

DISPOSITION: On or about 5-23-62, Rodelle Laboratories, Inc., filed a claim to the article. On 6-22-62, the case was transferred to the United States District Court, Dist. Wyo., pursuant to stipulation of the parties. On 8-14-62, an answer to the libel was filed by the claimant. On 12-18-62, the case came on for trial before the court. On 1-11-63, the court rendered the following findings of fact and conclusions of law:

KERR, *District Judge*:

FINDINGS OF FACT

"1. This case involves the seizure of a quantity of . . . 'Rodelle Sweet-Tone Preservative and Flavor Improver' under section 304 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 334.

"2. On March 12, 1962, the United States filed a Libel of Information in the San Antonio Division of the United States District Court for the Western District of Texas, alleging that the above-named product was misbranded while held for sale after shipment in interstate commerce within the meaning of 21 U.S.C. 334(a) and 343(a) in that its labeling, namely, the jar labels, contained statements which represented and suggested that the article improved the flavor of foods and was adequate and effective as a preservative and to prevent growth of mold and fermentation, generally in whipped cream goods, cream pie fillings, eclair fillings, pumpkin pie, crusts, candy centers, fondants, butter creams, and other foods; which statements were false and misleading since they were contrary to fact.

"3. Pursuant to said Libel and process thereunder, 14 gallon jars of the product described in the Libel were seized by the United States Marshal of the above-named district on March 16, 1962.

"4. Rodelle Laboratories, Inc., on May 23, 1962, intervened and filed claim to the goods.

"5. On June 22, 1962, pursuant to stipulation between the Government and Rodelle Laboratories, Inc., the case was transferred to this Court as authorized by 21 U.S.C. 334(b).

"6. On August 14, 1962, Claimant, Rodelle Laboratories, Inc., filed Answer to the Libel and trial by this Court was held commencing December 18, 1962.

"7. The parties stipulated that, on or about November 3 or 4, 1961, the article described in the Libel was shipped from Rodelle Laboratories, Inc., 2700 Arapahoe Street, Denver, Colorado, in interstate commerce via Red Ball Motor